



6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL- 9900-46-ORD; Docket ID No. EPA-HQ-ORD-2006-0756]

Notice of Extension of Public Comment Period on the Draft IRIS Carcinogenicity Assessment for Ethylene Oxide and Addition of Ethylene Oxide to October IRIS Bimonthly Meeting Agenda

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Extension of Public Comment Period to October 11, 2013, and Addition of Ethylene Oxide to October IRIS Bimonthly Meeting Agenda.

SUMMARY: EPA is announcing an extension of the public comment period for the IRIS external review draft carcinogenicity assessment titled, "Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide" (EPA/635/R-13/128a and EPA/635/R-13/128b) and the draft peer review charge questions. The original Federal Register notice announcing the public comment period was published on July 23, 2013. We are extending the deadline for this public comment period from September 5, 2013, to October 11, 2013, at the request of the American Chemistry Council and the Ethylene Oxide Sterilization Association, Inc. The draft assessment was prepared by the National Center for Environmental Assessment (NCEA) within the EPA Office of Research and Development (ORD). This draft assessment is not final as described in

EPA's information quality guidelines, and it does not represent and should not be construed to represent Agency policy or views.

Discussion of the draft IRIS carcinogenicity assessment for ethylene oxide will be included on the agenda of the IRIS bimonthly public meeting to be held on October 23–24, 2013, at EPA offices in Arlington, Virginia. Information on this meeting, including meeting location, time, registration, and participation procedures will be available at the IRIS website (<http://www.epa.gov/iris/publicmeeting/>).

DATES: The public comment period began on July 23, 2013, and is being extended to end on October 11, 2013. Comments should be in writing and must be received by EPA by October 11, 2013.

ADDRESSES: The draft “Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide” is available primarily via the Internet on the NCEA home page under the Recent Additions and Publications menus at <http://www.epa.gov/ncea>. A limited number of paper copies are available from the Information Management Team, NCEA; telephone: 703-347-8561; facsimile: 703-347-8691. If you request a paper copy, please provide your name, mailing address, and the document title. Comments may be submitted electronically via <http://www.regulations.gov>, by e-mail, by mail, by facsimile, or by hand delivery/courier. Please follow the detailed instructions provided in the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: For information on the federal docket, contact the Office of Environmental Information Docket; telephone: 202-566-1752; facsimile:

202-566-9744; or e-mail: Docket_ORD@epa.gov. For information on the IRIS bimonthly public meeting, contact Christine Ross, IRIS Staff, National Center for Environmental Assessment, (8601P), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW, Washington, DC 20460; telephone: 703-347-8592; facsimile: 703-347-8689; or e-mail: ross.christine@epa.gov. If you have questions about the document, contact Jennifer Jinot, National Center for Environmental Assessment; telephone: 703-347-8597; facsimile: 703-347-8690; or email: jinot.jennifer@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Information about IRIS

EPA's IRIS Program is a human health assessment program that evaluates quantitative and qualitative risk information on effects that may result from exposure to chemical substances found in the environment. Through the IRIS Program, EPA provides the highest quality science-based human health assessments to support the Agency's regulatory activities and decisions to protect public health. The IRIS database contains information for more than 500 chemical substances that can be used to support the first two steps (hazard identification and dose-response evaluation) of the human health risk assessment process. When supported by available data, IRIS provides health effects information and toxicity values for health effects (including cancer and effects other than cancer). Government and others combine IRIS toxicity values with exposure information to characterize public health risks of chemical substances; this information is then used to support risk management decisions designed to protect public health.

II. Extension of Comment Period

The EPA is extending the deadline for submitting comments on the draft “Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide” and on the draft peer review charge questions to October 11, 2013. The original deadline for comments was September 5, 2013. The EPA’s decision responds to requests to extend the comment deadline. The EPA believes that this extension will assist in providing an adequate amount of additional time for the public to review the drafts and to provide written comments.

III. Bimonthly Public Meeting

In addition to the extension to the public comment period announced in this notice, the draft assessment will be discussed at the first IRIS bimonthly public meeting scheduled for October 23–24, 2013. Information on this meeting, including meeting location, time, registration, and participation procedures will be available at the IRIS website (<http://www.epa.gov/iris/publicmeeting/>). The purpose of the IRIS public meeting is to allow all interested parties to present scientific and technical comments on the draft IRIS health assessment and charge questions to EPA and other interested parties attending the meeting.

IV. Peer Review

In addition to this public comment period, the draft assessment will be reviewed by the EPA’s Science Advisory Board (SAB) Chemical Assessment Advisory Committee (CAAC) for peer review. The EPA SAB is a body established under the Federal Advisory Committee Act with a broad mandate to advise the Agency on scientific matters. The public comment period and bimonthly public meeting announced in this notice are separate processes from the SAB/CAAC peer review. The SAB will schedule one or more public peer-review meetings

which will be announced in a separate Federal Register Notice at a later date.

V. How to Submit Technical Comments to the Docket at <http://www.regulations.gov>

Submit your comments, identified by Docket ID No. EPA-HQ-ORD-2006-0756 by one of the following methods:

- <http://www.regulations.gov>: Follow the on-line instructions for submitting comments.
- E-mail: Docket_ORD@epa.gov.
- Fax: 202-566-9744.
- Mail: Office of Environmental Information (OEI) Docket (Mail Code: 28221T), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460. The phone number is 202-566-1752.
- Hand Delivery: The OEI Docket is located in the EPA Headquarters Docket Center, EPA West Building, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The EPA Docket Center's Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is 202-566-1744. Deliveries are only accepted during the docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information. If you provide comments by mail or hand delivery, please submit one unbound original with pages numbered consecutively, and three copies of the comments. For attachments, provide an index, number pages consecutively with the comments, and submit an unbound original and three copies.

Instructions for submitting comments to the EPA Docket: Direct your comments to Docket ID No. EPA-HQ-ORD-2006-0756. Please ensure that your comments are submitted within the specified comment period. Comments received after the closing date will be marked “late,” and may only be considered if time permits. It is EPA’s policy to include all comments it receives in the public docket without change and to make the comments available online at <http://www.regulations.gov>, including any personal information provided, unless a comment includes information claimed to be confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through <http://www.regulations.gov> or e-mail. The <http://www.regulations.gov> website is an “anonymous access” system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through <http://www.regulations.gov>; your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA’s public docket visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>.

All documents in the docket are listed in the <http://www.regulations.gov> index. Although

listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in <http://www.regulations.gov> or in hard copy at the OEI Docket in the EPA Headquarters Docket Center.

Dated: August 19, 2013.

Lynn Flowers,
Acting Director, National Center for
Environmental Assessment.

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